

PATENT
J6877(C)
03-0379-HC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Dabkowski et al.
Serial No.: 10/764,114
Docket No. J6877(C)
Filed: January 23, 2004
For: MILD VISCOUS CLEANSING COMPOSITIONS WITH VERSATILE
COMPATABILITY AND ENHANCED CONDITIONING

Group: 1751
Examiner: Delcotto, Gregory R
Englewood Cliffs, NJ 07632
September 28, 2006

DECLARATION FILED UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Cinda Sue Carlson, a citizen of the United States, residing at 1176 Wenonah Avenue, Oak Park Illinois 60304, do hereby declare that:

1. I hold the degree of Masters in Science in Chemistry from Illinois State University and am a member of American Chemical Society, Society of Cosmetic Chemists and Sigma Xi, The Scientific Research Society.
2. I am presently employed as a Senior Project Scientist by Unilever Home and Personal Care USA in the Hair Development Group located at 3100 Golf Road, Rolling Meadows, Illinois 60008. I have worked in the Unilever Hair Development Group at Rolling Meadows since 2002.
3. I have read Dabkowski et al, U.S. Patent Application S.N. 10/764,114, filed January 23, 2004, of which I am a named Inventor.
4. The experiments described below were carried out under my supervision and are reported accurately herein.
5. Experiments were carried out to distinguish the present invention from the disclosures of Patel et al in US 6,165,454, Baravetto et al in US 6,174,522, and Fairley et al in US 2002/01922180. In particular, the experiments demonstrate significant differences in potential for ocular irritation as measured by the Fluorescein Leakage Assay between the types of surfactants used and their relative amounts disclosed in these compositions relative to the compositions disclosed in the Dabkowski et al application.
6. The specific examples selected from the above references were chosen because they are believed to represent the mildest and least irritating compositions to eyes among all the compositions disclosed in the references. They are the same examples previously evaluated for zein solubility as reported in an earlier declaration dated April 17, 2006.
7. The compositions given in Table 1 below were prepared according to the written descriptions given in each reference. The locations of these descriptions are identified by column and line numbers in the Table 1. Each composition is a "full formulation" from the patent examples identified using the same materials described in the reference. The methods of preparation were similar to those described in the references. However, some small modifications were made because of differences in available equipment. These process modifications are not expected to have any effect on the ocular irritation potential results because the compositions are isotropic (equilibrium) liquids.
8. Each composition of Table 2 was tested during the period August 30, 2006 to September 2, 2006 under identical conditions for the amount of sodium fluorescein that penetrates the cell junctions after standardized treatment with test compositions. The tests were carried out by Dr. Ruy Tchao of University of the Sciences in Philadelphia, Philadelphia College of Pharmacy. As discussed in Dabkowski et al (Page 26) Fluorescein leakage is a widely used

in-vitro method to assess to assess potential ocular irritation of surfactant containing cleansing compositions. The procedure employed is identical to that described in Dabkowski et al on pages 26 and 27 of the application. The results reported previously in example 1 for compositions prepared according to Dabkowski et al (SN 10/764,114 – Page 38, Ex 1A and Ex 1B) are also provided for comparison in Table 2. Finally, the results for positive and negative controls known to induce significant and negligible eye irritation respectively are set forth in last two rows of Table 2.

9. The % permeability values (initial, 24 hours and combined score) are collected in Table 2 below. The results indicate that all of the tested example compositions disclosed in the references cited in examination induce a % permeability around 10% at initial exposure however upon a 24 hour recovery period the permeability increases to levels well above 10% (combined score 40% and higher) that indicates moderate to significant irritation to eyes. In contrast compositions of Ex 1A and Ex 1B according to Dabkowski et al, U.S. Patent Application S.N. 10/764,114 induce a permeability of less than 10% immediately after initial exposure and remains below 10% at 24 hours recovery. The Dabkowski et al compositions are expected to be slight to non-irritant which is confirmed in practice (such compositions are currently sold as “no-tears” children’s shampoos by Unilever).
10. As expected, the Fluorescein Leakage Assay results discussed herein are consistent with the Zein Solubility Assay results communicated earlier in a Declaration dated April 17, 2006. Taken together, the results demonstrate that the compositions disclosed in the references cited in the Office Actions would be unsuitable for a shampoo or body wash intended not to irritate eyes or be ultra mild to skin such as a conditioning shampoo for children.
11. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this patent application or any patent issuing thereon.

Dated: 9/28/06

..... Cinda Sue Carlson
Cinda Sue Carlson

Table 1 Compositions Prepared

PATENT AND EXAMPLE NO.	INGREDIENTS	WT%	PREPARATION
<u>Patel et al Ex 33</u> US 6,165,454 Example 33 Table F Column 13	Water	To 100%	Basic Method described on column 8, line 61 to column 9, line 60
	SLES-2EO (28%)	43	
	CAP betaine (30%)	13.34	
	Acuyln® 22 (30%)	5	
	Dimethicone (60,000)	3	
	Preservative (Kathon CG)	0.1	
<u>Patel et al Ex 44</u> US 6,165,454 Example 44 Table G Column 15	Water	To 100%	Basic Method described on column 8, line 61 to column 9, line 60
	ALS (28%)	43	
	CAP betaine (30%)	16.67	
	Acuyln® 33 (28%)	7.14	
	TAB-2	2.5	
	Zinc Pyrithione "ZPT", 50%	2.0	
<u>Patel et al Ex 55</u> US 6,165,454 Example 55 Table H Column 15	Preservative (Kathon CG)	0.1	Basic Method described on column 8, line 61 to column 9, line 60
	Water	To 100%	
	SLES-2EO (28%)	43	
	Polyquaternium 7 (8%)	2.5	
	CAP betaine (30%)	13.34	
	CDEA	0.5	
	Acuyln® 33 (28%)	5.9	
	Dimethicone (60,000)	3.0	
	Preservative (Kathon CG)	0.1	
<u>Patel et al Ex 73</u> US 6,165,454 Example 73 Table K Column 19	DSDAC	0.2	Basic Method described on column 8, line 61 to column 9, line 60
	Water	To 100%	
	SLES-2EO (28%)	33.0	
	Polyquaternium 10 (100%)	0.35	
	Polyquaternium 7 (30%)	3.0	
	CAP betaine 30%	17.0	
	CDEA (90%)	0.6	
	Acuyln® 33 (28%)	5.89	
	Dimethicone (60,000)	3.5	
	DSDAC	0.25	
	Preservative (Kathon CG)	0.1	

Table 1 - Continued

<u>Baravetto et al Ex VI</u> US 6,174,522 Middle Table Column 24	Ammonium laureth-3 sulfate	14	Method of preparation described at column 23, line 40 to column 24, line 9
	Cocoamidopropylbetaine	2.7	
	Polyquaternium 10	0.15	
	Cocamide MEA	0.8	
	Ethylene glycol distearate	1.5	
	Dimethicone (1)	1.0	
	Dimethicone (4)	1.5	
	Perfume	0.7	
	DMDM Hydantoin	0.37	
	Water	To 100%	
<u>Baravetto et al Ex X</u> US 6,174,522 Middle Table Column 24	Ammonium laureth-3 sulfate	12.5	Method of preparation described at column 23, line 40 to column 24, line 9
	Cocoamidopropylbetaine	4.2	
	Polyquaternium 10	0.15	
	Cetyl alcohol	0.42	
	Stearyl alcohol	0.18	
	Ethylene glycol distearate	1.5	
	Dimethicone (1)	1.0	
	Dimethicone (4)	2.25	
	Perfume	0.7	
	DMDM Hydantoin	0.37	
	Water	To 100%	
<u>Fairley et al Ex 1</u> US2002/01922180 Table, Page 8 Example 1	Carbopol 980	0.4	Method of preparation as described at paragraph [0148]
	SLES-2EO	14.0	
	CAPB	2.0	
	Jaguar C13S	0.1	
	Perfume	0.6	
	Glydant plus	0.2	
	Soybean oil	3.0	
	Sodium Chloride	1.0	
	BHT	0.24	
	Water	To 100%	

Table 2. % Permeability based on Fluorescein Leakage Assay

COMPOSITION	% PERMEABILITY BASED ON FLUORESC EIN LEAKAGE ^a		
	Initial	After 24 hrs	Combined Score
Compositions Disclosed in References Cited in Office Action Mailed 7/14/2006			
Patel et al Ex 33	13.0+/-2.2	64.2+/-10.6	77.2
Patel et al Ex 44	8.4+/- 0.7	49.1+/- 3.5	57.5
Patel et al Ex 55	11.1+/- 1.7	60.4+/- 9.9	71.5
Patel et al Ex 73	9.2+/- 1.6	47.5+/- 3.4	56.7
Baravetto et al Ex VI	11.9+/- 1.5	43.1+/- 4.5	55.0
Baravetto et al Ex X	12.2+/- 2.5	28.2+/- 8.4	40.4
Fairley et al Ex 1	12.2+/- 0.8	62.6+/- 16.9	74.8
Composition According to Dabkowski et al SN 10/764,114			
Ex 1A (page 38)	6.0+/- 0.9	1.0+/- 0.4	7
Ex 1B (page 38)	7.8+/- 0.9	1.0+/- 0.5	8.8
Controls			
Positive (Sodium Dodecyl Sulfate Solution)	9.2+/-1.0	36.2+/-14.7	45.4
Negative (HBSS buffer solution)	0.2+/-0	1.0+/-0.3	1.2

- a) See p 26 of Dabkowski et al, U.S. Patent Application S.N. 10/764,114, filed January 23, 2004